EXHIBIT 355

Case: 1:17-md-02804-DAP Doc #: 1965-37 Filed: 07/23/19 2 of 28. PageID #: 167379

Mt. Vernon, Illinois Distribution Center

Quality System Procedure

Walgreens

Subject:		Orig	12/11/2006
Authorization of	Description Order Deliev	Page	1 of 2
Aumentication of	Prescription Order Policy	Rev Date	10/07/2013
Procedure Number	Inventory Controls Doc 1	Department	SAIL
Approved By	Dusty McCoy	Written By	Heather Smith

I. Purpose

A. To establish procedures for verifying questionable store order quantities on RX items.

II. Scope

A. This procedure covers the steps in verifying questionable store order quantities prior to order processing on RX items.

III. Procedure

- A. Responsibilities of the computer room personnel and SAIL team.—Prior to Order Processing
 - Once transmissions have been received from the stores to its fullest, query name SCORDRSREV
 is printed for the next process cycle date to be reviewed. Any RX order greater than 24 skus of
 one item should print on query in store numerical order along with SS items.
 - The CR/SAIL personnel working the query will review the listing. If there is a questionable quantity, the pharmacy is contacted at that store and the order is questioned. If the order is incorrect, the original order for the item(s) is deleted and rekeyed correctly.
 - 3. Once all orders have been reviewed for accuracy, the computer room personnel is notified to kick off Order Processing.
- B. Responsibilities of the RX team member personnel, Location Control and SAIL team—Stores Picking date
 - 1. As RX team members are picking orders, if an order seems questionable, SAIL office will be contacted via phone for order accuracy verification.
 - 2. SAIL team member contacts the pharmacy personnel at the store for order verification. If order is incorrect, a replenishment markdown is done on the billings by our Loc Control team and only the requested # of skus/cases is sent.
- C. Responsibilities of Walgreens Company
 - The Walgreens Strategic Inventory Management System will stop what would be considered suspicious controlled drug orders from being released for picking at the DC based on the algorithm that looks at past sales and order frequency.
 - 2. If we suspect a store order to be suspicious, the order will be cancelled and then reported to the FDA, the Board of Pharmacy, and the DEA for controlled substance within three business days.

Case: 1:17-md-02804-DAP Doc #: 1965-37 Filed: 07/23/19 3 of 28. PageID #: 167380

Walgreens

Mt. Vernon, Illinois Distribution Center Quality System Procedure

Subject:	Orig 12/11/2006
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Authentication of Prescription Order Policy	Rev Date 10/07/2013
Procedure Number Inventory Controls Doc 1	Department SAIL
Approved By Dusty McCoy	Written By Heather Smith

IV. Training

- A. To establish procedures that properly train, evaluate, and guide the team members on the process.
 - 1. The SAIL Function Manager will be responsible for the training and enforcement of all procedures.
 - 2. Training will be reviewed with all team members quarterly by the SAIL Manager.
 - 3. Procedures will be reviewed with recommended changes made and policies updated.

Inventory Controls Doc 1A

Suspicious Order Monitoring Program Policy and Procedures for the Pharmaceutical Integrity Team

This **policy** and specific **procedures** govern how controlled substance orders are processed and what steps are taken by the Pharmaceutical Integrity team to investigate orders of interest in the Controlled Substance Order Monitoring system (CSOM).

Overview

Walgreens Distribution Centers (DCs) must take reasonable measures to identify its customers, understand the <u>normal and expected</u> transactions conducted by those customers, and identify transactions involving controlled substances that are <u>suspicious</u> in nature. For the purpose of this document, a DC "customer" is an individual Walgreen pharmacy. Orders must be assessed to ensure that quantities of controlled substances ordered by a specific location are reasonable. In making these assessments, the DC may consider the pharmacy's clinical business needs, location, and population served. Walgreens *must report* to the DEA any order that is determined to be suspicious.

How to Identify Normal, Expected Transactions

The following elements allow the Pharmaceutical Integrity team to understand and identify normal and expected transactions, which assists in identifying potentially suspicious transactions.

- Accumulation of Receipts over time period: The CSOM accumulates the amount of each controlled substance over a specified limitation period (i.e. over the last six weeks).
- Ceiling Limit: Data mining is done across Walgreens retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive in a rolling six week time period, based on statistical linear regression. The analysis compares like pharmacies across the country based on prescription volume and determines, by drug, an amount that would represent an unusual quantity.

Factors for Assessing all Orders to Determine Whether the Transaction is Reasonable

The following elements allow the Pharmaceutical Integrity team to assess <u>all</u> orders for controlled substances to determine whether the transaction is reasonable. This analysis is done for all controlled substance orders regardless of quantity.

- Available to Order: The pharmacy is allowed to order the quantity that is left "open," which is the ceiling limit, set through the analytical technique identified above, minus any accumulation of receipts over the six weeks along with any currently open orders that are in the supply pipeline. For example, if the pharmacy has a ceiling limit for Drug X of 10,000 dosage units, an accumulation of 5,000 dosage units, and 1,000 dosage units on order, the amount available to order is 4,000 (10,000-(5,000+1,000)).
- Central Monitoring and Control Dashboard: The Pharmaceutical Integrity team is able to centrally monitor when a particular pharmacy is approaching a percentage of their ceiling limit (e.g. 75%) for any selected controlled substance as an early warning system to alert the corporate team of a potential concern. The team can then contact the pharmacy to determine if there is a concern or if the demand is justifiable.
- Tolerance Limits: Tolerance limits are in place to identify any unusual activity on an order-byorder basis to ensure that no individual order exceeds a given statistical limit. This calculation is based on that pharmacy's past order history.

Reporting to DEA and State Agencies

Reporting is required to DEA and the applicable state agency when a transaction takes place that involves an extraordinary quantity of a controlled substance. The processes and policies put in place by Walgreens prevent any shipments from occurring that involve an extraordinary quantity; however, should any such order take place, it must be investigated to determine whether it is suspicious. If during the process the 'order of interest' is determined to be valid, documentation is required before the ceiling limit can be increased and additional orders can be shipped. If during the course of the investigation the order is deemed suspicious, the order is not shipped and it is reported to DEA and the state agency, if applicable.

In the event that a pharmacy requests that an order be shipped which exceeds the ceiling or tolerance limit, the Pharmaceutical Integrity team considers clinical business needs, location, and population served, in addition to other factors, prior to approving the order.

Using the Central Monitoring and Control Dashboard for Controlled Substance Order Monitoring

Process Overview

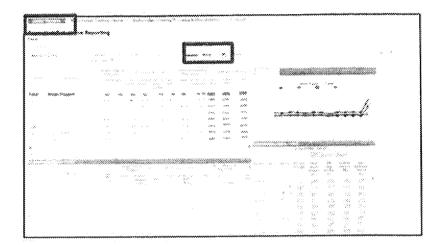
- Dedicated analysts investigate any order deemed an "order of interest." After investigation, any order of interest deemed suspicious will be reported to DEA.
- Pharmaceutical Integrity analysts are assigned specific markets so that the market is viewed
 in its entirety, as well as at the district, store and individual order level.
- Managers provide process and analytical support as needed.
- * Each market is analyzed using the CSOM. The CSOM systematically highlights orders approaching tolerance and/or ceilings so that analysts can investigate the appropriateness of these orders.
- Analysts are able to drill down into the store ordering system to further evaluate the appropriateness of these orders.
- Analysts communicate with Pharmacy Supervisors to further understand the appropriateness
 of these orders, e.g. stores that support hospice centers, oncology centers, etc.
- Loss Prevention and Senior Management are involved as needed for escalations.

Process Steps

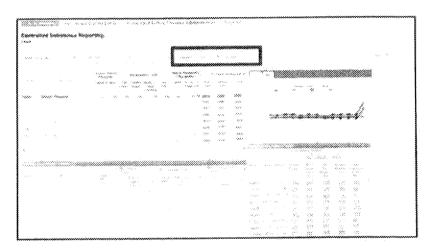
Use the following steps to access the system to identify orders of interest.

- To access the CSOM, type "CSOKPI" in your web browser; save it to your favorites for future use.
- Sign in with your authenticator.
- Use the screen shots below to guide you through the process of reviewing orders.

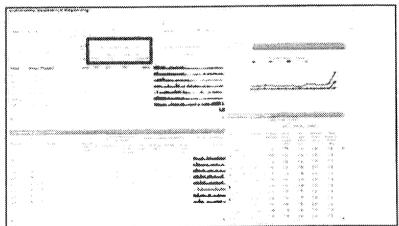
From the Order
Review home
screen, use the
Location drop down
to choose Market.



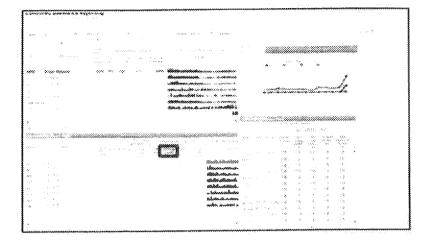
Enter the Market number and press enter.



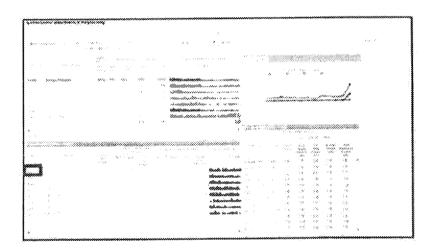
- Scroll over in the top pane to view the number of System Reduced orders in this market.
- The bottom left pane shows the list of districts in this market.
- The bottom right pane shows the list of drugs ordered in this market.



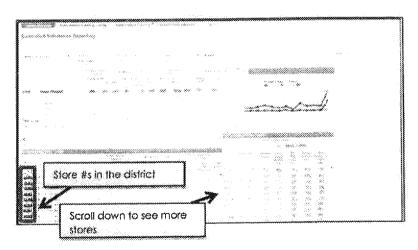
4. Click the Ceiling
Limit box in the
System Reduced
Order in the bottom
left pane to see the
rank order of districts
within a market
(most reduced, in
descending order.)



5. To view more details for a particular district, click the district number.

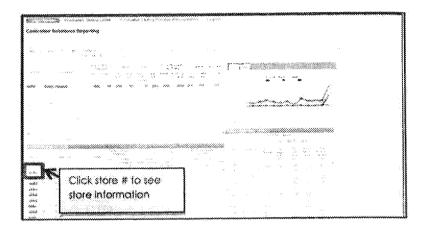


6. The system displays all stores in this district. All panes show data for this district only.

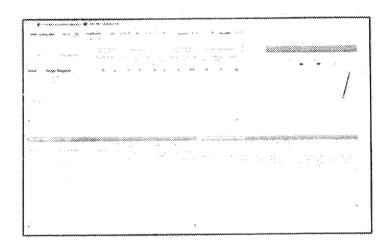


Proprietary & Confidential, Property of Walgreen Co.

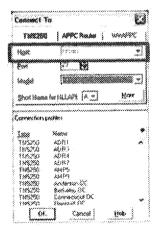
7. Click the Ceiling
Limit box in the
System Reduced
Order in the bottom
left pane to see the
rank order of stores
within a District. To
see entries with a
value other than 0 in
the Ceiling Limit
column for a specific
store, click the store
number.



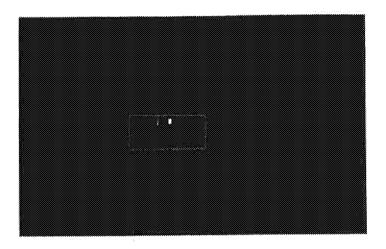
 Now all panes display specific data for the store you selected. Analyze the data by focusing on System Reduced Order(s) reduced for ceiling limit.



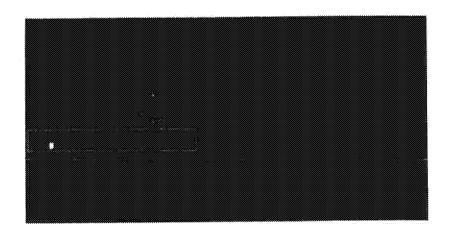
 To evaluate each order, launch the application that connects to the Walgreens stores Strategic Inventory Management System (SIMS) on the store AS/400 server and enter the store number in the Host field.



10. You are now connected to SIMS. Log in with your corporate sign-on.



11. Type Call ORCO400 on the selection or command line to access the store's SIMS Support screens.



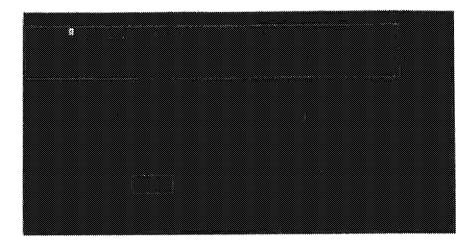
- 12. To view the order history of the item, query SIMS by entering any of the following for the item:
- WIC: Walgreens Item Code
- UPC: Universal Product Code
- PLN: Planogram Link Number, an inventory control number

and press enter.



6

- This displays the current open order.
 You can analyze the results of the previous query.
- Press F16 to view historical orders for this item.
- Other function keys and selections drill down into more details about how and why the order was derived. Note that all details are not specific to Rx or controlled substances.
- 14. If, after using your professional judgment and pharmacy operations experience, you believe this order needs further investigation, email the Pharmacy Supervisor from the Pharmacy Integrity mailbox, using this email template.
- Remember to work all appropriate drugs into one email.
- Please add your initials only to your email.
- List store number in tracker.



Pharmacy Supervisor,

Store (xxxxx) has been flagged by Walgreens Rx integrity for higher orders of interest on WiC: (xxxxxx) item: (any controlled substance). The Walgreens DC will not fill any orders going forward unless the following information can be ascertained.

- o What steps is the store taking to ensure Good Faith Dispensing?
- When was the last store visit performed by District Supervision?
- Provide a detailed explanation (+/-) of any adjustments made in SIMS?
- What is the percentage of 3rd party sales to cash on (insert controlled substance)?
- Are there any unusual geographical distances between patient, pharmacy, and prescriber that cannot be reasonably explained?
- Is there a noticeable trend in controlled substance prescribing by one prescriber or for a large number of patients?
- Provide the Top 5 prescribers in the area prescribing (insert controlled substance)

The information mentioned above should be provided to us within the next 48 hours so we may process these orders in a timely matter.

Thank you,

Pharmacy Integrity Analyst

- 15. After you have completed the process for one drug, move to the next on the list for the market you are reviewing.
- 16. After completing all drugs, move to the next market.

- 17. Evaluate the response from the Pharmacy Supervisor using these points:
 - If the survey is incomplete, reply to the Pharmacy Supervisor for additional information.
 - If the survey is complete:
 - Is there a legitimate reason for exceeding the ceiling limit?
 - o Examples of legitimate reasons for an increase in the ceiling limit include:
 - ✓ Oncology site
 - ✓ Hospice site
 - ✓ Recent buy-out or closure of a competitor
 - ✓ Patient has insurance change leading to transfer to Walgreens
 - ✓ New medical center (ER) in area
 - ✓ Change in state or third party formulary, drug shortage, etc.
 - a If, in your professional judgment, the pharmacy warrants a change in the ceiling limit, forward suggested changes to your manager.
 - Are the reasons provided inadequate?
 - Examples of potentially inadequate reasons for surpassing the ceiling limit include:
 - ✓ Favored drug of a particular prescriber
 - ✓ New pain clinic in the area
 - ✓ Good Faith Dispensing practices at the store are inadequate
 - ✓ Multiple patients with the same prescriber
 - ✓ Patients with multiple prescribers for the same prescription
 - If, in your professional judgment, the order is confirmed to be suspicious, prepare the fax template as shown below to review with your manager before faxing it to the DEA and state agency, if appropriate.

ste E	Stores	Address	ICity	State	219	OEA 8	Drug Heme	NOC #	Package Size	Quantity ordered is bottle
innessa i	~~~~	Store Address		i zamaz.	8888	sense DEAM	Mydrocoddone/APAP 10/S00M8	00591-0540-08	500	30
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18. Escalations

- · Use your professional judgment and pharmacy operations experience when reviewing orders.
- You should escalate:
 - Unusual trends in the historical data
 - Patterns in drug families in certain markets and communities
- Escalate these instances and any questions that are not covered in these policies and procedures to your manager.
- Loss Prevention and Senior Management will be involved as needed for escalations.
 - * Note that escalations may lead to policy re-education, other store level training, Loss Prevention investigations, and disciplinary action, when appropriate.

Mt Vernon Stores - DC 88008 - Product Ordering Process

Prior to the RX phase out to Amerisource Bergen (ABC), Sunday – Thursday, a member of the SAIL team or the Computer Room would verify receiving stores RX transmissions for orders that would be processed at 3 pm CST that afternoon for next day picking.

This is based off of the stores weekly warehouse schedule that is transmitted to the stores from the DC standard shipping schedule ex shown below for #1444 showing that this store is a day 4 pick for schedule category (SS & RX = A) for a fleet delivery.

IT. VERNO	M			ST	HDF	ARD S	HIF	PI	NG SC	HEDUL	Ε			M	UF DIAM	MING
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To	Ind			Ε			0	ŋ	Pct	Pot	Ind	F	Ind	75	Ť	Tre
	S				37		3		100	100						N

Below is a breakdown of roughly 4 stores suggested transmission information and how we would know if we were missing their RX suggested transmission or not or if they were a store already phased out to ABC.

Ex #1913 has "ABC" listed instead of RX, thus alerting DC personnel no RX transmission was needed from store.

Ex #1444 & #1679 If there were numbers listed to the left of the word RX, then we received that stores suggested RX transmission. If there were no numbers listed, then we knew that we were missing that stores RX suggested transmissions and a ticket would be opened with our 2nd level As400 Support Team

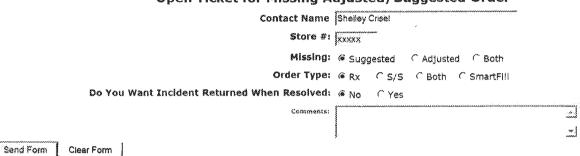
Case: 1:17-md-02804-DAP Doc #: 1965-37 Filed: 07/23/19 14 of 28. PageID #: 167391

Inventory Controls Doc1B

	27	R	26	RX	1140421	1140421	03:49:40	0
01444								
	7	R	1247	55	1140421	1140421	02:00:06	0
	7	R	42	ŘX	1140421	1140421	62:00:08	0
	7	R	3	EXP	1140421	1140421	02:00:08	0
01679								
	73	R	1716	\$\$	1140421	1140421	03:49:47	0
	73	R	51	RX	1140421	1140421	03:49:51	0
01913	<i>*************************************</i>				v			
	58	R	1730	\$\$	1140421	1140421	03:49:54	0
	58	R	3	EXP	1140421	1140421	03:49:58	0
				ABC				
02019	t							
	73	R	1701	SS	1140421	1140421	03:49:58	Ö
	73	R	44	ŘX	1140421	1140421	03:50:01	Ũ
	73	8	2	EXP	1140421	1146421	03:50:01	£

To open a ticket for missing transmission with 2^{nd} Level

Open Ticket for Missing Adjusted/Suggested Order

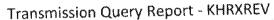


Mt Vernon Stores – DC 88008 – Order Error Process

Once it has been confirmed that the adjusted transmissions are across, the SAIL or the Computer Room TM will start reviewing stores' RX transmissions and see if there any RX items that have been ordered greater than 16 skus of one wic by 1 store.

If there is an item that appears to be questionable, a call will be made to the pharmacy of the respective store to review the order and make the change if needed, prior to OP-order processing.

Below are 3 different examples of items that were ordered incorrectly at the store level that were caught and changed at the DC level on the respective stores' Open Order Select screen for the order # that was transmitted



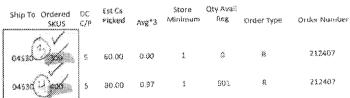






Transmission Query Report - KHRXREV

Sub ttem?	ttem #	Bern Description
	¢73656	B-D-U/FN SYR SHORT 310GA 1CC 100S
	676986	WALG 30G 1CC INSULIN SHRT SVR 1005,



Now with the recent ABC phase out, the report is still ran daily, however the DC personnel may or may not see order errors from the stores on RX items remaining in DC. Same process as mentioned above would still take place.

List 1 Chemical Storage & Handling

Walgreens	List 1 Chemical Storage & Handling
Supply Chain & Logistics, Distribution Centers	Document #: ALL_LIST 1 CHEM_1.6.1
Date Issued: 01/31/16	Revision #: 1.6.1
Approved By: Process Engineering	Page 1 of 13

Table of Contents

1.0	Laibose tatacionatucintationistesiminete territore divinuitativa vicus vi	or L
2.0	Responsibilities & General Expectations	2
3.0	Definitions	2
4.0	Safety Guidelines	., 2
5.0	Licensing Requirements	3
6.0	Tools, Equipment, and Other Provisions for Team Members	., 3
7.0	Receiving	4
8.0	Location Control	, <u>.</u>
9.0	Replenishment / Delayer / Detrash	ک پاردو
10.0	Picking	. 5
11.0	Tote Audit	6
12.0	Shipping	6
13.0	Modified Post Billing (MPB)	.,.6
14.0	Damaged Goods Processing.	7
15.0	Physical Inventory	8
16.0	Report Generation ,	8
17.0	Process Flows	.11
18.0	Reference Documents	. 13
19.0	Acknowledgement	. 13
Docur	nent History	1.3

ALL_LIST 1 CHEM_1.6.1

Page 1 of 13

List 1 Chemical Storage & Handling

1.0 Purpose

The purpose of this document is to define high-level Standard Operating Procedures (SOPs) for distribution center Team Members responsible for receiving, storing, locating, replenishing, picking, auditing, and shipping LIST 1 CHEMICAL merchandise (e.g., Pseudoephedrine). This SOP is intended to supplement, not replace, existing SOPs in each functional area.

Most requirements dictated by government regulations are focused towards instances where less than case quantities (i.e. split case quantity, piece quantity) are accessible to Team Members or passers-by.

2.0 Responsibilities & General Expectations

- 2.1 Distribution Center (DC) and Fleet Management are responsible for ensuring compliance with the policies and procedures defined in this SOP. It is also the responsibility of Management to ensure that all Team Members handling LIST 1 CHEMICAL merchandise are fully trained and are in compliance with the policies and procedures defined in this SOP.
- 2.2 The License Administration department within Accounting Shared Services Management is responsible for applying for and maintaining licensing required for storing and handling LIST 1 CHEMICAL merchandise within the Walgreens Supply Chain and Logistics network. Additional licensing requirements may apply on a state-by-state basis.
- 2.3 Team Members are expected to abide by the policies, procedures, and guidelines established within this document.
- 2.4 Team Members are responsible for obtaining necessary supplies from the designated supply areas.
- 2.5 As government regulations or company guidelines are changed, it is the responsibility of the Walgreens Legal and Compliance teams to cascade updates to the DC and Fleet Management teams.
- 2.6 Formalized revisions to this SOP document will be made by the Engineering, Compliance & Safety Departments. Suggestions for revisions are encouraged from all business units, including DC operations, Field operations, and personnel within support functions.
- 2.7 Asset Protection is responsible for validating adherence to the security measures outlined in the SOP.

3.0 Definitions

ACCESS CONTROL: Typical access control provisions include demising walls or fencing, locked pedestrian entrance and exit locations (doors, turnstiles, etc.), and card/badge access readers at entry points.

Contact Asset Protection with any additional questions.

CAMERA SURVELLANCE: Typical camera surveillance provisions include cameras linked to the Asset Protection department's monitoring system.

LIST 1 CHEMICAL: A chemical specifically designated by the Administrator of the Drug Enforcement Administration that, in addition to legitimate uses, is used in manufacturing a controlled substance/illicit drug in violation of the Controlled Substances Act, 21 U.S.C. § 802.

VAWD: Verified-Accredited Wholesale Distributors

4.0 Safety Guidelines

A Team Member does the following to ensure their safety and the safety of others:

- **4.1** Reads and follows safety notices and other posted information.
- **4.2** Observes and follows all safety instructions, signs, and operational procedures.
- 4.3 Immediately reports all unsafe conditions, hazards, or equipment to his/her manager,

ALL_LIST 1 CHEM_1.6.1

Page 2 of 13

List 1 Chemical Storage & Handling

Case/Item Handling Safety Rules:

- 4.4 Utilize "power zone" when lifting, turning, or carrying totes. The "power zone" is close to the body, between mid-thigh and mid-chest height. Comparable to the strike zone in baseball, this zone is where arms and back can lift the most with the least amount of effort.
- 4.5 Only authorized Team Members are allowed to use material handling equipment. When using material handling equipment, follow all rules and regulations regarding the specific equipment.

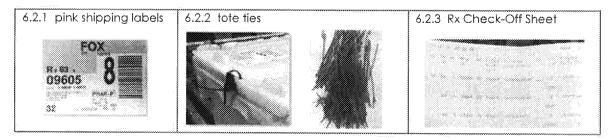
5.0 Licensing Requirements

In order to comply with Federal licensing requirements for storing and handling **LIST 1 CHEMICAL** merchandise, a DC must obtain one of the following:

- 5.1 LIST 1 CHEMICAL Permit (Preferred)
- **5.2** Drug Enforcement Administration (DEA) Registration
 - 5.2.1 Enables the storage and handling of federally regulated Schedule III-V Controlled Substances (CIII-V).
 - 5.2.2 Incorporates additional regulatory requirements as well as a greater degree of government oversight and scrutiny. If a DC does not store and handle federally regulated CIII-V merchandise, these additional DEA constraints will add unnecessary ongoing operational costs. Furthermore, a DC with a DEA registration will need to obtain permission from the DEA prior to storing LIST 1 CHEMICAL merchandise within a cage (with ACCESS CONTROL).

6.0 Tools, Equipment, and Other Provisions for Team Members

- 6.1 Per federal regulations cited within section 18.1.2, background checks must be included with the screening process for selecting Team Members who directly handle or have direct access to LIST 1 CHEMICAL merchandise that is less than a case quantity (i.e. split case quantity, piece quantity).
 - 6.1.1 These functions include, but are not limited to, Location Control, Split Case Replenishment, Split Case Picking, Detrash, and Audit.
 - 6.1.2 DC Management teams must retain a record of employee background checks for duration of employment.
 - 6.1.3 Walgreens will conduct **annual background checks** for existing employees who directly handle **LIST 1 CHEMICAL** merchandise. This is also a **VAWD** accreditation requirement (where applicable).
 - 6.1.4 Federal regulations require that any employee who has knowledge of diversion from his/her employer by a fellow employee must report such information to Management. In addition, in the event an employee commits a felony while employed with the company, he/she must inform Management.
- 6.2 Team Members must have all of the following to perform tasks involving LIST 1 CHEMICALS:



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Page **3** of **13**

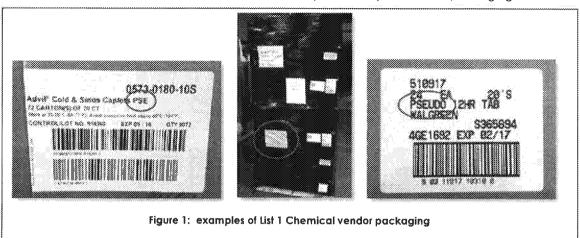
List 1 Chemical Storage & Handling

7.0 Receiving

Annual background checks are not required for Team Members unloading or receiving full case quantities of LIST 1 CHEMICAL merchandise. The check-in process can occur while product is staged on the receiving dock.

7.1 Trailer Unload

- 7.1.1 For security purposes, many vendors will load LIST 1 CHEMICAL merchandise in the middle or front of a trailer to deter theft. This provision makes it difficult for LIST 1 CHEMICAL merchandise to be stolen in instances where the integrity of trailer security is compromised.
- 7.1.2 LIST 1 CHEMICAL merchandise should be clearly marked by the vendor packaging.



7.2 Product Check-In

7.2.1 An alert (red blinking indicator) on the SIMS receiving home screen designates a load containing LIST 1 CHEMICAL merchandise. [NOTE: Within SIMS, a fuchsia highlight of Freight-Bill number and WIC now indicates an item is Top 1K. Previously, this would have indicated an item was Regular Rx, C3-5, or PSE.]

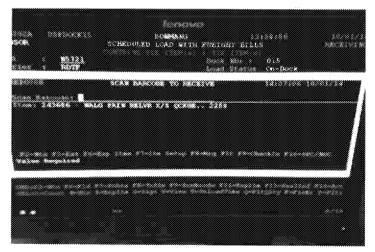


Figure 2: List 1 Chemical alert on SIMS receiving screen

ALL_LIST 1 CHEM_1.6.1

Page **4** of **13**

List 1 Chemical Storage & Handling

8.0 Location Control

- 8.1 Team Members performing this function will be in direct contact with individual units of LIST 1 CHEMICAL merchandise and must receive an annual background check.
- 8.2 Split Case Location Assignment (SIMS 1 & SIMS 2 DCs)
 - 8.2.1 Split case merchandise must be located in an area of the warehouse that has **ACCESS CONTROL** and **CAMERA SURVEILLANCE**. This enables the DC to guard against theft and diversion.
- 8.3 Split Case Location Assignment (SLS DCs)
 - 8.3.1 Split case merchandise must be located in the SPS carousels and must have **CAMERA SURVEILLANCE**. This process is deemed compliant because the stored merchandise is not accessible to Team Members or passers-by.
- 8.4 Full Case Location Assignment (SIMS 1 & SIMS 2 DCs)
 - 8.4.1 Full Case merchandise must be stored in a pallet or hand-stack location with **CAMERA SURVEILLANCE**. **ACCESS CONTROL** provisions are preferred, but not required.

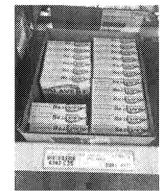


Figure 3: split case location (SIMS 1 & SIMS 2 DCs)

- 8.4.2 Asset Protection Solutions must be made aware of LIST 1 CHEMICAL locations without ACCESS CONTROL and must validate that the location has continuous security camera coverage. In addition, the location must be 10' or higher from the ground to limit pedestrian access to the merchandise.
- 8.5 Full Case Location Assignment (SLS DCs)
 - 8.5.1 Full case **LIST 1 CHEMICAL** merchandise will be located in the ASRS in the same manner as all other full case products. This process is deemed compliant because the stored merchandise is not accessible to Team Members or passers-by.

9.0 Replenishment / Delayer / Detrash

9.1 Full Case Replenishment

9.1.1 Team Members performing this function within an area of ACCESS CONTROL must receive an annual background check. Annual background checks are not required for Team Members replenishing full case locations outside of a controlled access area.

9.2 Split Case Replenishment

9.2.1 Team Members performing this function will be in direct contact with individual units of **LIST 1 CHEMICAL** merchandise and must receive an annual background check.

9.3 Detrash (SIMS 2 & SLS DCs)

- 9.3.1 Team Members performing this function will be in direct contact with individual units of **LIST 1 CHEMICAL** merchandise and must receive an annual background check.
- 9.3.2 Detrash stations used to process LIST 1 CHEMICAL merchandise must have ACCESS CONTROL and CAMERA SURVEILLANCE.

10.0 Picking

10.1 Full Case Picking

10.1.1 Team Members performing this function within an area of ACCESS CONTROL must receive an annual background check. Annual background checks are not required for Team Members picking from full case locations outside of a controlled access area.

10.2 Split Case Picking

10.2.1 Team Members performing this function will be in direct contact with individual units of **LIST 1 CHEMICAL** merchandise and must receive an annual background.

ALL_LIST 1 CHEM_1.6.1

Page 5 of 13

List 1 Chemical Storage & Handling

10.2.2 A shipping tote must be sealed with tote ties (reference section 7.2.2). Tote ties will prevent tampering once the container is no longer within the area of **ACCESS CONTROL** and **CAMERA SURVEILLANCE** (i.e. conveyance, accumulation, sortation, divert, and loading).

11.0 Tote Audit

- 11.1 Team Members performing this function will be in direct contact with individual units of LIST 1

 CHEMICAL merchandise and must receive an annual background check.
- 11.2 Audits for totes containing LIST 1 CHEMICAL merchandise must be completed in an area with ACCESS CONTROL and CAMERA SURVEILLANCE. A best practice is to complete the audit process prior to the tote leaving the controlled access pick area. This enhances the operation's ability to properly control and monitor who is handling LIST 1 CHEMICAL product.
- 11.3 After audit completion, a shipping tote must be re-sealed with tote ties.

12.0 Shipping

12.1 Loading

- 12.1.1 LIST 1 CHEMICAL merchandise can be shipped via fleet or courier along with totes and cases of non-LIST 1 CHEMICAL merchandise. Therefore, all Shipping Team Members must receive training for the loading of LIST 1 CHEMICAL merchandise.
- 12.1.2 Annual background checks are not required for Team Members performing this function.
- 12.1.3 Each Team Member loading trailers must have an "Rx Check-Off Sheet" for their assigned stores/routes/doors. These reports can be generated by the Computer Room team or the Shipping Department Management team.
- 12.1.4 The Team Member must verify receipt of each pink label tote on the report by initialing the "Ck" column.

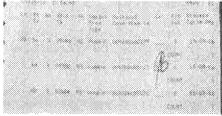


Figure 4: initialled "Rx Check-Off Sheet"

- 12.1.4.1 Discrepancies between the "Rx Check-Off Sheet" and physical verification must be brought to the attention of the Function Manager for investigation.
- 12.1.4.2 Team Members that identify totes missing one or both tote ties must notify their Function Manager immediately. The Function Manager must have the tote audited for accuracy prior to shipment.

12.2 Case Hospital

- 12.2.1 Annual background checks are not required for Team Members performing this function.
- 12.2.2 Team Members that identify totes missing one or both tote fies must notify their Function Manager immediately. The Function Manager must have the tote audited for accuracy prior to shipment.

13.0 Modified Post Billing (MPB)

- 13.1 Shipments must include a supplemental manifest page (i.e. WPPB201 report) citing the LIST 1 CHEMICAL parcels (i.e. pink label totes). Drivers are expected to account for all listed parcels and obtain a signature from a representative of the Store Management Team at the time of delivery.
- 13.2 Any LIST 1 CHEMICAL discrepancies (i.e. missing, damaged, or tampered) reported to S.A.I.L. must be investigated through completion.

ALL_LIST 1 CHEM_1.6.1

Page 6 of 13

List 1 Chemical Storage & Handling

14.0 Damaged Goods Processing

Non-salable LIST 1 CHEMICAL merchandise should be dispositioned using the flowchart in figure 5.

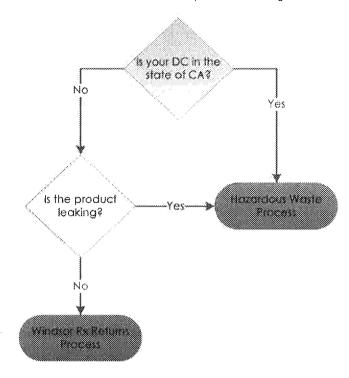


Figure 5: List 1 Chemical disposition flowchart

Windsor Rx Returns Process



Hazardous Waste Process

As a DC Management team configures the process to handle damaged **LIST 1 CHEMICAL** merchandise at their facility, they must account for Federal requirements related to **LIST 1 CHEMICAL** merchandise, as well as all other applicable waste disposal regulations in their state.

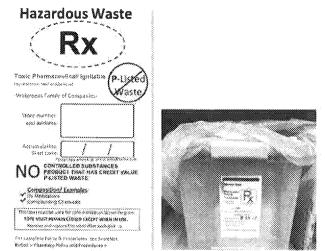
The facility will set up a hazardous waste tote inside the LIST 1 CHEMICAL pick area.

- **14.1** The hazardous waste tote must be labeled with the appropriate "General Rx" hazardous waste label.
 - 14.1.1 The tote label must be dated when the first waste item is placed in the tote.

ALL_LIST 1 CHEM_1.6.1

Page 7 of 13

- 14.1.2 The tote label must be replaced after the waste vendor performs a pickup.
- 14.2 Each waste item must be placed in a zip seal bag.
- 14.3 Write the following information on the zip seal bag (either directly on the bag or on a blank thermal that can be attached directly to the individual bag):
 - 14.3.1 NDC
 - 14.3.2 Drug name
 - 14.3.3 Manufacturer
 - 14.3.4 Quantity
- 14.4 Only the same type of item (same WIC/NDC) can be placed inside the bag.
- 14.5 The Function Manager assigned to the LIST 1 CHEMICAL area must communicate with the



List 1 Chemical Storage & Handling

Figure 6: Hazardous Waste label

Environmental Champion that waste from the LIST 1 CHEMICAL pick area requires pickup.

- 14.6 Pseudoephedrine (PSE) is a Controlled Substance in the following States:
 - 14.6.1 Mississippi and Oregon CIII; prescription only.
 - 14.6.2 Arkansas, Georgia, Illinois, Iowa, Kansas, Louisiana, Minnesota, Missouri, New Mexico, Oklahoma, West Virginia and Wisconsin CV.
 - 14.6.3 The waste vendor will need to know <u>in advance</u> that waste Controlled Substances <u>generated in these States</u> requires pickup so that they can plan accordingly.
- 14.7 Team Members handling hazardous wastes will need to be trained in accordance with the environmental hazardous waste procedure for Processing Damages. The DC Environmental Champion will assist in performing TM training.
- 14.8 Additional guidance on this topic is available from the Compliance department.

15.0 Physical Inventory

- 15.1 Team Members performing physical inventory will be in direct contact with individual units of LIST 1 CHEMICAL merchandise and must receive annual background checks.
- **15.2** Every **LIST 1 CHEMICAL** item should be counted at least once every 2 weeks. Any discrepancies must be communicated to the Function Manger and investigated through resolution.

16.0 Report Generation

Any facility that holds a **LIST 1 CHEMICAL** permit is subject to inspection by the DEA. Reports are available within Walgreens' existing systems for use during a DEA audit.

Ways to identify LIST 1 CHEMICAL merchandise in the AS/400:

16.1 Dedicated opstudy and product category

OPSTUDY	PRODUCT CATEGORY (prod cat)
144 ALLERGY	004 – PSE
184 COUGH & COLD	011
015 RX MISC	007
207 PEDIATRICS	005

16.2 Product Type = PSE LIST ONE

ALL_LIST | CHEM_1.6.1

Page **8** Of **13**

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List 1 Chemical Storage & Handling

Generating LIST 1 CHEMICAL reports from the AS/400 menu:

- 16.3 Scroll down to PSE Reporting and select.
- 16.4 Key in the item WIC and date range on the control line.
 - 16.4.1 To see **all the activity** in the date range, leave the last field on the control line, "A/R/S/I/Blank(all)", blank,
 - 16.4.2 To see the **shipping activity** only, enter "S" in the last field.
 - 16.4.3 To view information for a **specific shipment**, enter "X" to select the shipment you are interested in. F3 to return to main screen.
 - 16.4.4 To view receiving activity, enter "R" in the A/R/S/I/Blank(all) control field on the main screen.
 - 16.4.5 To see **detailed receipt information**, enter "X" on a selected receipt you are interested in. F3 to return to main screen.
 - 16.4.6 Selecting "A" or "I" in the A/R/S/I/Blank(all) field will select only history **records for adjustments** (from Audit Trail) or inventory levels.
 - 16.4.7 Entering "X" on an adjustment or inventory line, will take you to screen displaying **detail for that particular adjustment** or that day's inventory.
 - 16.4.8 To generate a **print report** for any of the detail options, just do a Print Screen of the detail screen.
 - 16.4.9 To generate a complete report of all the activity within a date range, or just shipping, receiving, adjustments or inventory activity within a date range, enter F7 from the main screens.
- **16.5** Questions about generating reports must be directed to Supply Chain and Logistics: Information Systems Engineer Team.

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Figure 7: "Received Items" Report

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Page 9 of 13

List 1 Chemical Storage & Handling

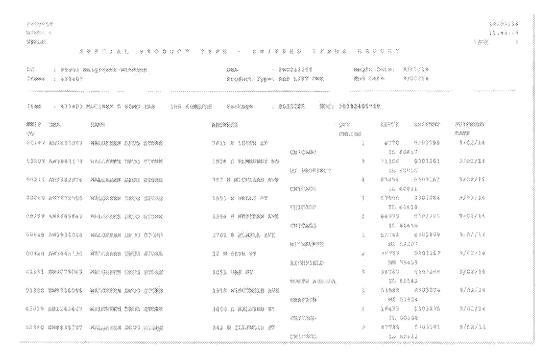
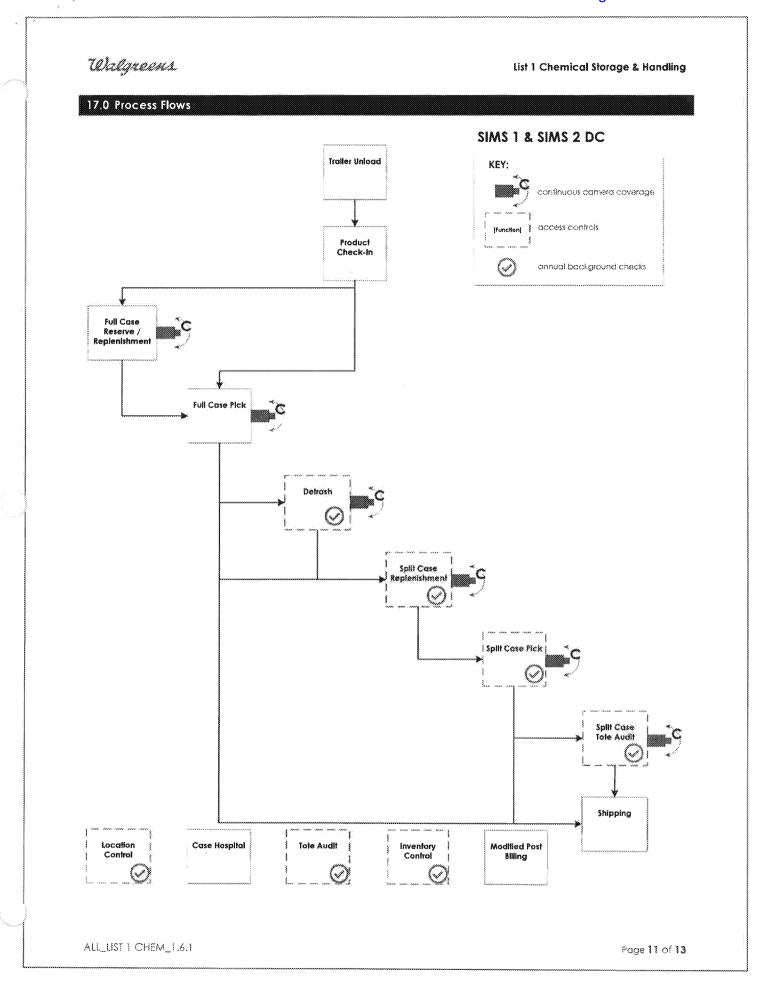
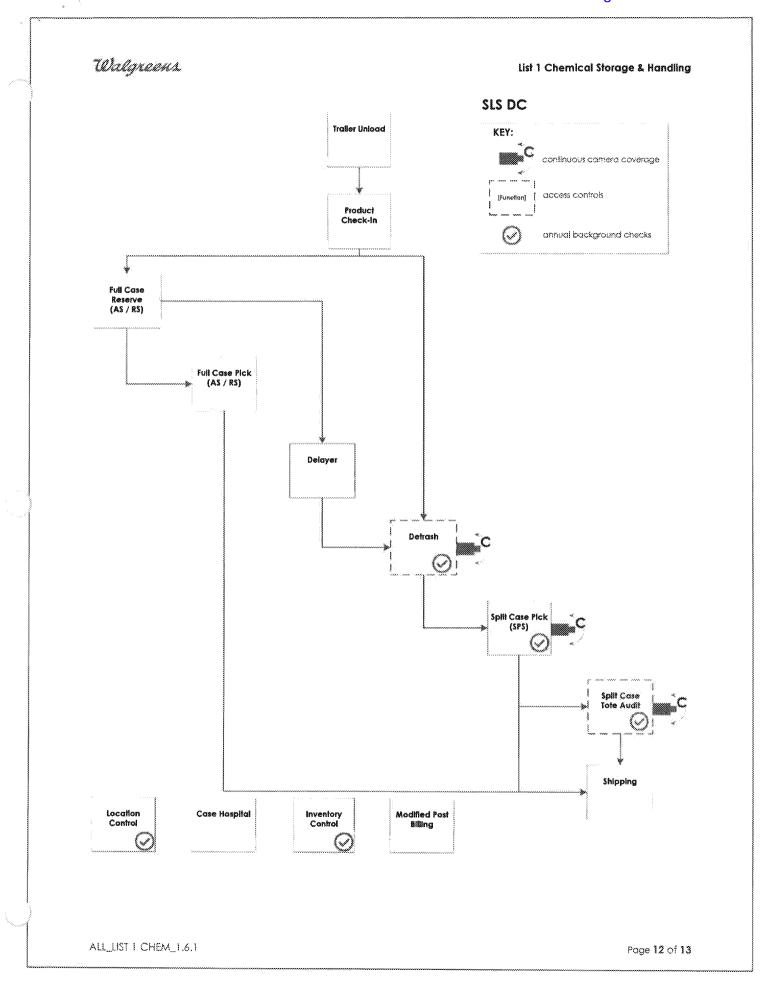


Figure 8: "Shipped Items" Report

ALL_LIST 1 CHEM_1.6.1 Page 10 of 13





List 1 Chemical Storage & Handling

18.0 Reference Documents

- 18.1 Copies of the following federal regulations are on file with the Walgreens Legal Department and are applicable to the storage, handling, and delivery of LIST 1 CHEMICAL merchandise.
 - 18.1.1 21 CFR 1309.71 General security requirements
 - 18.1.2 21 CFR 1309:72 Felony conviction; employer responsibilities
 - 18.1.3 21 CFR 1309.73 Employee responsibility to report diversion

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Statement of Compliance:	
1Procedure for LIST 1 CHEMICAL SH	have read and understand the above Standard Operating
Team Member Signature	Date
Supervisor Signature	Date

Document History

Version #	Version Date	Description of Change	Author
1.0	09/15/14	Original version	Brit Videbeck
1.1	10/05/14	Added photos and observations from Windsor DC	Brit Videbeck
1.2	10/22/14	Incorporate Walgreens Compliance input	Stan Zagula
1.3	10/28/14	Incorporate DC team input	Brit Videbeck
		Redacted – Attorney Client Privileged	
1.5	04/11/15	Added damaged product procedures	Dan Leskovec
1.6	10/02/15	Included operational feedback, Redacted - Attorney Client Privileged Redacted - Attorney Client Privileged updated damaged product procedures (Gina Hastreiter), and AP changes (Josh Durkey)	Kristy Chandler
1.6.1	01/22/16	Incorporated feedback from DC GMs and DC Admins	Kristy Chandler

ALL_LIST 1 CHEM_1.6.1

Page **13** of **13**